## 510(k) Summary

APPLICANTS NAME AND ADDRESS

Hamilton Medical AG

Via Nova

CH-7403 Rhaezuens

Switzerland

APPLICANTS CONTACT PERSON

Mr. Andreas Scheibe Phone: +41 81 6606010 Fax: +41 81 6606020

e-mail: ascheibe@hamilton-medical.ch

APPLICANTS CONTACT PERSON IN

THE USA

Hamilton Medical Inc. Mr. David Thompson Phone: 775-858-3200 Fax: 775-856-5621

e-mail: thompson@hammed1.com

DATE THE SUMMARY WAS

**PREPARED** 

08/07/2003

**COMMON NAME** 

Continuous Ventilator

PROPRIETARY NAME

RAPHAEL

PURPOSE OF SUBMISSION

New device

CLASSIFICATION

Name: Ventilator, Continuous (per 21 CFR 868.5895)

Panel: Anesthesiology

Code: CBK

REGULATORY STATUS

1. Current Device Class: Class 2

2. Performance Standards & Special Controls: None Exist

LEGALLY MARKETED DEVICES TO WHICH HAMILTON MEDICAL IS CLAIMING SUBSTANTIAL **EQUIVALENCE** 

Galileo

510(k)#: K 001686

-Manufactured by Hamilton Medical AG

Dräger Evita 2 Dura

510(k)#: K 970165

-Manufactured by Dräger Medizintechnik

Siemens Servo-i

510(k)#: K 010925

-Manufactured by Siemens-Elema AB

Puritan Bennett 840 510(k)#: K984535 -Manufactured by Nellcor Pruritan Bennett

### DEVICE DESCRIPTION

The RAPHAEL is an microprocessor controlled critical care ventilator system.

RAPHAEL supplies mandatory or spontaneous breaths with the preset oxygen concentration to provide continuous ventilation for adult, pediatric, and infant patients weighing between 5 and 200kg.

It is powered by AC with a battery backup to protect against power failure or unstable power and to facilitate intrahospital transport.

The user interface consists of a LCD-display, a display panel keyboard to open windows, and central rotary dial knob (press-and-turn element) for selecting, setting, and confirming inside the window.

The user provides inputs to the RAPHAEL microprocessor system through the keys and the press-and-turn element. RAPHAEL provides audible and visual patient-related, and ventilator-related alarms.

Accessories to connect RAPHAEL to the patient airway opening are the same as for GALILEO, found substantially equivalent in the 510(k) file number K001686.



### INTENDED USE

The RAPHAEL ventilator is designed for intensive care ventilation of adult, pediatric, and infant patients weighing between 5 and 200 kg.

### INTENDED OPERATOR

The RAPHAEL ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician.

## INTENDED PATIENT POPULATIONS

Patients with body weight between 5 kg and 200 kg.

### INTENDED USE ENVIRONMENT

The RAPHAEL ventilator is intended for use at the bedside and for transport within a hospital or hospital-type facility, provided compressed gas is supplied.

The RAPHAEL ventilator is not to be used in the presence of flammable anesthetic agents.

The RAPHAEL ventilator is not to be used in a magnetic field of a MRI equipment.

### SUBSTANTIAL EQUIVALENCE

The functionality for the RAPHAEL critical care ventilator is equivalent to the GALILEO and partly also to Servo i, Evita 2 Dura and Puritan Bennett 840.

The design of RAPHAEL and the pneumatic concept are similar to those of GALILEO.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

OCT 2 2 2003

Mr. J. David Thompson Hamilton Medical, Incorporated Post Office Box 30008 Reno, Nevada 89520

Re: K022679

Trade/Device Name: Raphael Ventilator

Regulation Number: 868.5895

Regulation Name: Continuous Ventilator

Regulatory Class: II Product Code: CBK Dated: July 21, 2003 Received: July 30, 2003

# Dear Mr. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <a href="http://www.fda.gov/cdrh/dsma/dsmamain.html">http://www.fda.gov/cdrh/dsma/dsmamain.html</a>

Sincerely yours,

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital, Infection Control and Dental Devices Office of Device Evaluation Center for Devices and

Radiological Health

Enclosure

Page 1 of 1

### INDICATIONS FOR USE STATEMENT

510(k) Number:

K022679

Device Name:

RAPHAEL ventilator

Indication for Use:

The RAPHAEL ventilator is a continuous ventilator designed for ventilation of adult, pediatric, and infant patients weighing between 5 and 200 kg. The RAPHAEL ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician. The RAPHAEL ventilator is intended for use in a hospital or hospital-type facility, including use at a patient bedside or for

intra-facility transport, provided compressed gas is supplied.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER	PAGE IF NECESSARY)
--	--------------------

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital,

Infection Control, Dental Devices

510(k) Number: <u>4022</u>674

Prescription Use: 1 (Per 21 CFR 801.109) OR

Over-The-Counter Use \_